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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,435	03/13/2000	HIDEHISA ASADA	00177/530985	9095

513 7590 10/21/2003

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EXAMINER	
NOLAN, PATRICK J	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/21/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/508,435	ASADA ET AL.	
	Examiner	Art Unit	
	Patrick J. Nolan	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Serial Number: 09/508,435
Art Unit: 1644

Part III DETAILED ACTION

1. Claims 23-42 are pending.

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8-7-03 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:
A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 23-42 are rejected under 35 U.S.C. § 103 as being unpatentable over Hunt et al. (U), of record, in view of Harlow et al, newly cited.

Hunt et al., teaches an immunoassay specific for gamma-BNP, also known as Pro-BNP, wherein said immunoassay uses a first antibody reactive with human alpha-BNP, also known as mature or BNP-32, and a second antibody reactive with PreProBNP or gamma-BNP

and not reactive with alpha-BNP (see Table 1 and Material and Methods in particular). The gamma-BNP antibody was made from an oligopeptide which was not part of alpha-BNP so it would inherently not bind alpha-BNP and it would inherently bind amino acid sequence shown by amino acid residues 27-102 of SEQ ID NO. 1 because the antibody was made from residues 27-39 of SEQ ID NO. 2, which is the amino acid sequence of SEQ ID NO.1 which is a nucleic acid sequence. Lastly Hunt et al., teaches that the antibodies are labeled with a radioactive isotope.

The claimed invention differs from the prior art teachings by the recitation of using a sandwich assay rather than an RIA. However, Harlow et al., specifically teaches sandwich assays are one of the most useful of the immunoassays and they are used primarily to determine antigen concentration in unknown samples and that either monoclonal or polyclonal antibodies can be used and that a major advantage is that the antigen does not need to purified prior to use and that the assays are very specific. In addition, the claimed invention differs from the prior art teachings only by the recitation of a kit.

Therefore, one skilled in the art at the time the invention was made would have been motivated to switch the RIA taught by Hunt et al., with a sandwich assay to detect mammalian γ-BNP derivatives because the detection of both Pro-BNP and BNP-32 was correlative for congestive heart failure as taught by Hunt et al., (page 1179-1180), and the use of a sandwich assay are advantageous in detecting unknown concentrations of unpurified antigens. Lastly, one skilled in the art would have recognized the usefulness of supplying an antibody BNP test kit for use in diagnostic assays, wherein said kit had two antibodies, one for ProBNP and the other for BNP-32, especially since Hunt et al., teaches that there is a specific correlation between ProBNP and BNP-32 and patients with congestive heart failure. Test kits are compounds packaged for the convenience of the practitioner and are conventionally made to reproducibly obtain results under test conditions and it is conventional to assemble all necessary reagents, including antibodies, buffers and standards for the convenience of the practitioner and commercial expediency. Furthermore, the preamble reciting "A kit for ..." does not convey any patentable weight to the actual components of the kit itself.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

5. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973.

Serial Number: 09/508,435
Art Unit: 1644

Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
October 20, 2003